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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,166	03/17/2004	James Robert Schwartz	9184M	4150

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EXAMINER

ARNOLD, ERNST V

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/802,166	SCHWARTZ ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 and 7-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

### **DETAILED ACTION**

The Examiner acknowledges receipt of Applicant's remarks filed on 5/30/2006. Applicant's arguments have been carefully considered by the Examiner but have not been found to be persuasive. Claims 5 and 6 have been cancelled. Accordingly, claims 1-4 and 7-25 are pending.

#### **Withdrawn rejections:**

1. Claims 1-25 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicant has amended the claims to overcome this rejection and the Examiner withdraws the rejection.
2. Claims 1-3, 7, 9, 14-20 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 38-41, 43-50 and 54-56 of copending Application No. 10/742,557.
3. Claims 1, 7, 8, 10, 11 and 14-16 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 11-13 and 17-19 of copending Application No. 10/392,422. Applicant has filed a terminal disclaimer and the rejection is withdrawn.
4. Claims 1-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6-15, 17-22 and 26-32 of copending Application No. 11/216,520. Applicant has filed a terminal disclaimer and the rejection is withdrawn.
5. Claims 1-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 8-28 of copending

Application No. 11/100648. Applicant has filed a terminal disclaimer and the rejection is withdrawn.

6. Claims 1-3, 5, 14-17 and 23-24 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-9, 13 and 23-25 of copending Application No. 10/803,126. Applicant asserted that the present invention is not directed to a composition containing an augmentation factor greater than 1 and the '126 co-pending composition is not directed to or required to have zinc lability of greater than about 15% for a zinc-containing layered material. Applicant asserts that augmentation and relative zinc lability are two distinct components. It is the Examiner's position that the amended claims are no longer obvious and the rejection is withdrawn.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 7-8, 12-17 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Cilley et al. (4,933,101).

Instant claim 1 is drawn to a composition comprising a zinc-containing layered material and a surfactant wherein the zinc-containing layered material has a relative zinc lability of greater than about 15%. The Examiner sought guidance from the

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specification on the definition of a zinc-containing layered material. Applicant defines a zinc-containing layered material (Page 5, lines 11-16) as:

Many ZLM's occur naturally as minerals. Common examples include hydrozincite (zinc carbonate hydroxide), basic zinc carbonate, aurichalcite (zinc copper carbonate hydroxide), rosasite (copper zinc carbonate hydroxide) and many related minerals that are zinc-containing. Natural ZLM's can also occur wherein anionic layer species such as clay-type minerals (e.g., phyllosilicates) contain ion-exchanged zinc gallery ions. All of these natural materials can also be obtained synthetically or formed in situ in a composition or during a production process.

Applicant further provides synonyms for basic zinc carbonate (Page 6, lines 3-7):

Basic zinc carbonate, which also may be referred to commercially as "Zinc Carbonate" or "Zinc Carbonate Basic" or "Zinc Hydroxy Carbonate", is a synthetic version consisting of materials similar to naturally occurring hydrozincite. The idealized stoichiometry is represented by  $Zn_3(OH)_6(CO_3)_2$  but the actual stoichiometric ratios can vary slightly and other impurities may be incorporated in the crystal lattice

Applicant provides commercial resources for basic zinc carbonate, which is provided as zinc carbonate Page 5, lines 31-33 and page 6, lines 1-2):

Commercially available sources of basic zinc carbonate include Zinc Carbonate Basic (Cater Chemicals: Bensenville, IL, USA), Zinc Carbonate (Shepherd Chemicals: Norwood, OH, USA), Zinc Carbonate (CPS Union Corp.: New York, NY, USA), Zinc Carbonate (Elementis Pigments: Durham, UK), and Zinc Carbonate AC (Bruggemann Chemical: Newtown Square, PA, USA).

Therefore, the Examiner interprets insoluble zinc carbonate particles to be a zinc-containing layered material.

Cilley et al. disclose a detergent composition comprising from about 0 to 5% detergent surfactant (instant claims 7-8); from about 0.25% to 10% of a thickening

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agent; and an amount of an insoluble inorganic zinc compound that will provide the composition with from about 0.01 to about 1.0% zinc (Column 24, lines 10-23). A number of zinc compounds can be used including zinc basic carbonate (Column 22, lines 50-58 and column 24, lines 30-34). The zinc compound can be zinc carbonate (Column 24, lines 35-36). An example of a composition comprising insoluble zinc carbonate particles having a particle size less than 250 microns is provided (Column 22, line 60-column 23, line 31). The surfactant is an anionic surfactant (Column 24, lines 60-64). Since the disclosure of Cilley et al. has the same zinc-containing layered material as the instantly claimed invention then it would inherently have the same relative zinc lability of greater than about 15% to greater than about 20% and to greater than about 25% and thus meet the limitations of instant claims 1 and 12-17. The Patent and Trademark Office is not equipped with the scientific equipment to compare the composition of Cilley et al. to the instantly claimed invention but when the compositions are comprised of the exact same materials and would inherently have the exact same properties then the burden is appropriately shifted to the Applicant to demonstrate that they are not the same.

**Response to arguments:**

Applicant asserted that Cilley teaches non-analogous art. However, the claims read on a composition and the composition of Cilley reads on the instant invention and the rejection is maintained.

***Claim Rejections - 35 USC § 102***

Claims 1-4 and 7-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Gavin et al. (WO 01/00151).

Gavin et al. disclose a topical anti-dandruff composition for treating microbes comprising from 0.001 to 10% zinc pyrithione; from 0.001 to about 10% of a zinc salt and an anionic detergent surfactant for a topical carrier thus reading on instant claims 1-3, 5, 7 and 8 (Claim 1). The zinc salt can be the insoluble particulate zinc carbonate anticipating instant claim 14 (Claim 6). Since the disclosure of Gavin et al. has the same zinc-containing layered material as the instantly claimed invention then it would inherently have the same relative zinc lability of greater than about 15% to greater than about 20% and to greater than about 25% and thus meet the limitations of instant claims 12-17. The pH of the compositions ranges from about 2 to about 10 and most preferably from about 5.5 to about 7.5 thus within the scope of instant claims 9-11 (Page 7, lines 7-9). The concentration of the anionic surfactant ranges from about 5% to about 50% by weight of the composition consequently reading on instant claims 4 and 6 (Page 8, lines 10-16). The addition of cationic deposition polymers (instant claim 18) is anticipated (Page 20, lines 30-34-page 25, line 30). The addition of conditioning agents (instant claim 19) is anticipated (Page 35, line 12- page 47, line 16). Suspending or thickening agents are anticipated and crystalline suspending agents are preferred thus reading on instant claims 20-22 (Page 18, line 27-page 20, line 28) Methods pertaining to treating microbial infections preferably related to dandruff and treating athlete's foot, a contagious fungal infection, are provided hence anticipating instant claims 23-25 (Claim 9).

**Response to arguments:**

Applicant asserted that the insoluble particulate zinc carbonate disclosed in Gavin et al. is not synonymous with the zinc layered material of the instant invention. The Examiner has carefully considered this argument. However, the Examiner is maintaining his position that zinc carbonate and basic zinc carbonate are synonymous as evidenced by the material safety data sheet from Mallinckrodt Baker, Inc; a global supplier of high purity fine chemicals. The MSDS for zinc carbonate states that basic zinc carbonate is a synonym and has a chemical formula of  $3\text{Zn}(\text{OH})_2 \cdot 2\text{ZnCO}_3$  (MSDS zinc carbonate, page 1 of 7). And because the terms are synonymous, the composition of Gavin et al. reads upon the instant invention and the Examiner maintains the rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7-17, 19-21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiese (US 5,227,156) in view of Blank et al. (5,883,085).

Wiese discloses an anti-dandruff shampoo comprising up to about 40% anionic, nonionic, amphoteric and zwitterionic surfactants; from about 0.1 to about 2% zinc pyrithione; from about 0.001% to about 1% of a zinc compound selected from the group consisting of a zinc salt of an organic acid, a zinc salt of an inorganic acid, zinc oxide,



zinc hydroxide, and mixtures thereof and water (Abstract; column 1, lines 35-47; column 2, lines 1-32; column 3, lines 32-45; and claim 1, for example). Wiese discloses that a preferable pH of the composition is neutral (7.0) to slightly acidic pH, which is within the scope of the instant claims (Column 3, lines 64-66). Wiese further provides examples of shampoo compositions comprising a polymeric suspending agent, hydroxypropyl methylcellulose (Column 4, line 38).

Wiese does not expressly disclose zinc carbonate as one of the zinc compounds in the composition although Wiese does disclose zinc compounds of organic acids.

Blank et al. discloses topical skin formulations comprising zinc carbonate as a skin protectant (Column 8, lines 30-42 and claim 14, for example).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the anti-dandruff shampoo of Wiese by adding zinc carbonate as suggested by Blank et al to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Wiese suggests that zinc compounds of organic acids can be used and zinc carbonate is the zinc salt of carbonic acid. One of ordinary skill in the art would have been motivated to select zinc carbonate because Blank et al. disclose that zinc carbonate is beneficial to the skin as a protectant (Column 8, lines 30-42).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because

every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

**Response to arguments:**

Applicant asserted that the zinc carbonate disclosed by Blank et al. is not the same zinc carbonate required by the instant invention. The Examiner respectfully disagrees with this opinion and has supplied the MSDS of zinc carbonate establishing that zinc carbonate and basic zinc carbonate are synonymous. The rejection is maintained for this reason.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

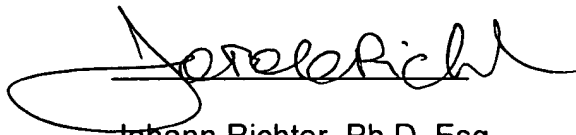
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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